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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/388,090	09/01/99	JACKSON W	7969-082

EXAMINER

HM12/0606

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NEW YORK NY 10036-2711

DEVI,S

ART UNIT	PAPER NUMBER
1641	6

DATE MAILED: 06/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/388,090	Jackson et al.
Examiner	**Group Art Unit**
S. Devi, Ph.D.	1641

☒ Responsive to communication(s) filed on *03/14/2000.*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-47* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-47* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Restriction / Election

1) Claims 1-47 are under prosecution.

2) **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your election responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3) Via the response filed 03/14/2000 (paper no. 3), Applicants elected, with traverse, to prosecute the subject matter of invention III, claims 37-41 and 44. While initiating a search on the claimed DNA sequences, it was discovered that the DNA sequence claimed in some claims is identified as an amino acid sequence in the Applicants' Sequence Listing and the polypeptide sequence claimed in certain claims is identified as a DNA sequence. For instance, claims 38-41 encompass an isolated DNA having the sequence of SEQ ID NO: 7. However, SEQ ID NO: 7 is identified as an amino acid sequence in the Applicants' Sequence Listing. Similarly, claims 5, 6, 8, 9, 11-14, 22, 28, 42 and 46 recite or encompass a polypeptide comprising a sequence of SEQ ID NO: 8. However, SEQ ID NO: 8 is identified as a DNA sequence in the Applicants' Sequence Listing. Applicants are invited to clarify the issue and/or amend the claims so that a meaningful search can be performed.

Further, claim 24 is improperly dependent from claim 21. It appears that claim 24 should have depended from claim 22 or claim 23. For the restriction requirement set forth below, it is assumed that claim 24 depends from claim 22 or 23 and not claim 21.

Ms. Geraldine Baldwin was informed of this inconsistency in a telephone interview conducted on 25 May 2000.

4) Upon further review of Applicants' disclosure, the restriction requirement has been modified to the extent indicated below. The restriction requirement mailed 02/14/2000 is hereby

vacated. Applicants are given a full opportunity to re-elect in accordance with the restriction requirement set forth below. The Office regrets any inconvenience this may have caused to the Applicants. For the purpose of the restriction requirement set forth below, SEQ ID NO: 8 is viewed as a polypeptide sequence and SE ID NO: 7 is viewed as a nucleic acid sequence. Based on Applicants' clarification, amendment and/or response to this Office Action, claims encompassing these SEQ ID numbers would be reshuffled to include them under proper invention groups.

5) Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 5, 6, 8 and 9, drawn to an NGSP polypeptide having the sequence comprising SEQ ID NO: 4, and a fragment thereof, classified in class 530, subclass 350.

II. Claims 5, 6, 8 and 9, drawn to an NGSP polypeptide having the sequence comprising SEQ ID NO: 6, and a fragment thereof, classified in class 530, subclass 350.

III. Claims 5, 6, 8 and 9, drawn to an NGSP polypeptide having the sequence comprising SEQ ID NO: 8, and a fragment thereof, classified in class 530, subclass 350.

IV. Claims 11 and 12, drawn to an antibody that specifically binds the NGSP polypeptide comprising a sequence of SEQ ID NO: 4 or a fragment thereof, classified in class 530, subclass 388.4.

V. Claims 11 and 12, drawn to an antibody that specifically binds the NGSP polypeptide comprising a sequence of SEQ ID NO: 6 or a fragment thereof, classified in class 530, subclass 388.4.

VI. Claims 11 and 12, drawn to an antibody that specifically binds the NGSP polypeptide comprising a sequence of SEQ ID NO: 8 or a fragment thereof, classified in class 530, subclass 388.4.

VII. Claims 38, 39 and 40, drawn to an isolated DNA having SEQ ID NO: 1, a fragment or complement thereof, classified in class 536, subclass 23.1.

VIII. Claims 38, 39 and 40, drawn to an isolated DNA having SEQ ID NO: 2, a fragment or complement thereof, classified in class 536, subclass 23.1.

IX. Claims 38, 39 and 40, drawn to an isolated DNA having SEQ ID NO: 3, a fragment or complement thereof, classified in class 536, subclass 23.1.

X. Claims 38, 39 and 40, drawn to an isolated DNA having SEQ ID NO: 5, a fragment or complement thereof, classified in class 536, subclass 23.1.

XI. Claims 38, 39 and 40, drawn to an isolated DNA having SEQ ID NO: 7, a fragment or complement thereof, classified in class 536, subclass 23.1.

XII. Claims 42 and 43, drawn to a method of producing an immune response comprising immunizing an animal with the NGSP polypeptide having a SEQ ID NO: 4 or a fragment thereof, classified in class 424, subclasses 190.1 and 249.1.

XIII. Claims 42 and 43, drawn to a method of producing an immune response comprising immunizing an animal with the NGSP polypeptide having a SEQ ID NO: 6 or a fragment thereof, classified in class 424, subclasses 190.1 and 249.1.

XIV. Claims 42 and 43, drawn to a method of producing an immune response comprising immunizing an animal with the NGSP polypeptide having a SEQ ID NO: 8 or a fragment thereof, classified in class 424, subclasses 190.1 and 249.1.

XV. Claim 44, drawn to a plasmid, classified in class 435, subclass 27.

XVI. Claim 45, drawn to an antagonist, classified in class 530, subclass 300.

XVII. Claim 46, drawn to a method for identifying compounds which interact with the NGSP polypeptide having the sequence comprising SEQ ID NO: 4, and a fragment thereof, classified in class 435, subclass 7.2.

XVIII. Claim 46, drawn to a method for identifying compounds which interact with the NGSP polypeptide having the sequence comprising SEQ ID NO: 6, and a fragment thereof, classified in class 435, subclass 7.2.

XIX. Claim 46, drawn to a method for identifying compounds which interact with the NGSP polypeptide having the sequence comprising SEQ ID NO: 8, and a fragment thereof, classified in class 435, subclass 7.2.

XX. Claim 47, drawn to a method for identifying an agent that is useful as a diagnostic, prophylactic or therapeutic agent against *Neisseria* infection comprising contacting a cell, classified in class 435, subclass 7.32.

Claims 1-4, 7, 14-21, 22-27 and 28-35 are linking claims and will be joined with one of inventions I, II and III, if elected.

Claims 10, 13 and 36 are linking claims and will be joined with one of inventions IV, V and VI, if elected.

Claims 37 and 41 are linking claims and would be joined with one of inventions VII, VIII, IX, X and XI, if elected.

6) Inventions I through IX are distinct from one another. Inventions I-III, inventions IV-VI, inventions VII-XI, invention XV and invention XI are drawn to distinct products: polypeptides; antibodies, nucleic acids, a plasmid and an antagonist. These products are distinct from one another structurally, physicochemically, functionally, immunologically and/or biologically. The polypeptides of invention I-III can be produced without using the nucleotide sequences of invention VII-XI, for example, by chemical synthesis.

Inventions XII and XIII, and inventions XVII-XIX and invention XX are directed to three independent and distinct methods, which differ from one another in method steps, parameters and reagents or compositions used, and ultimate goals accomplished. The methods for identifying compounds, or an agent are unrelated to the methods of producing an immune response in an animal by immunization.

Although the polypeptides of inventions I, II and III belong to the same class/subclass, these polypeptides comprise sequences that are structurally or chemically distinct from one another. Similarly, although inventions VII through XI belong to the same class/subclass, these DNAs comprise sequences that are structurally or chemically distinct from one another. The antibodies of inventions IV through VI differ from one another in their immunologic or binding specificity.

Inventions I and XII, inventions II and XIII, and inventions III and XIV are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be

practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the polypeptides of inventions I, II and III can be used in a materially different process, for example, as sources of coating antigens in an *in vitro* diagnostic assay to measure polypeptide-specific antibodies.

Inventions I and XVII, inventions II and XVIII, and inventions III and XIX are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the polypeptides of inventions I, II and III can be used in a materially different process, for example, as sources of immunogens in laboratory animals to raise polypeptide-specific antiserum reagents.

The products of inventions IV-VI, the products of inventions VII-XI, the products of inventions XV and XVI are unrelated to the methods of inventions XII-XIV and the methods of XVII -XX, because the products of inventions IV-VI, VII-XI, XV and XVI are not required to practice the methods of inventions XII-XIV and inventions XVII-XX.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification/subclassification and divergent subject matter, and since a search performed for one would not be co-extensive for the other, restriction for examination purposes as indicated is proper.

7) Claim 3 is generic to a plurality of disclosed patentably distinct species comprising *Neisseria ovis, Neisseria lacunata, Neisseria osloensis, Neisseria bovis* and *Neisseria gonorrhoeae*. Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

9) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

10) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. A telephone message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SD

S. Devi
Patent Examiner
May 2000

RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER: Dr. S. Devi

ART UNIT: 1641

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 305-3704

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